

REMARKS

Claims 1-57 are pending. Claims 12, 13, 33, 34 and 51-53 are canceled without prejudice. Claims 1, 4, 10, 31, 35, 45, 46, 54 and 56 are amended.

Claim 1 is amended to include the limitation “wherein an ectopic beat is tracked.” Support for this limitation can be found in the specification at page 5, lines 12-19; page 7, line 20 through page 8, line 4; and original claim 1. Claims 1, 10, 54 and 56 are amended to recite a “single ECG signal.” Support for this limitation can be found in the specification at, for example, page 11, lines 5-6; page 12, lines 13-16; and page 16, lines 19-21. Support for the amended claim 31 limitation “single heartbeat signal” can be found in the specification at page 11, lines 5-6; page 12, lines 13-16; and page 16, lines 19-21. Claims 4, 45 and 46 have been amended to independent claim format. The additional claim 31 amendments and the claim 35 amendment are added for purposes of clarity.

The Two Notices of Withdrawal From Issue Under 37 CFR 1.313

Applicant received two Notices of Withdrawal From Issue Under 37 CFR 1.313, each date-stamped July 21, 2004. One of the Notices (“Notice 1”) provides that the application was withdrawn from issue after payment of the issue fee due to unpatentability of one or more claims. The other Notice (“Notice 2”) provides that the application was withdrawn from issue in response to a petition by the Applicant prior to payment of the issue fee. Because the Applicant has not petitioned for withdrawal from issue, we believe that Notice 2 was sent in error. Applicant requests that the Examiner clarify the record in regard to these Notices.

Objections to the Claims

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Claims 4-6, 21-24, 27-30 and 45-49 have been found allowable if rewritten in independent claim form. Claims 4, 45 and 46 have been amended to independent claim format. Accordingly, the objection to claims 4-6, 45 and 46 should be withdrawn. Applicant will hold amendment of claims 21-24, 27-30 and 47-49 in abeyance pending a final disposition of the independent claims from which these claims depend.

The Provisional Rejection for Double Patenting Under 35 U.S.C. §101

Claims 51-53 of the instant application have been provisionally rejected for statutory double-patenting in view of claims 77-79 of co-pending application Serial No. 10/618,441 (“441 application”). Claims 51-53 have been canceled. Accordingly, this provisional rejection should be withdrawn.


The Provisional Rejection for Obviousness-type Double Patenting

Claims 10, 15, 16, 25, 56 and 57 have been provisionally rejected for obviousness-type double patenting over claims 74-76 of the ‘441 application. Enclosed herein is a terminal disclaimer, which obviates this rejection.

The Rejection Under 35 U.S.C. §102

Claims 1-3, 7-20, 26, 31-44 and 50-57 have been rejected under 35 U.S.C. §102(e) as being anticipated by Mlynash et al., U.S. Patent No. 6,615,075 (“Mlynash”). According to the Examiner, Mlynash discloses aligning an arrhythmia signal and a QRST template and calculating cross-correlation coefficients.

Independent claims 1, 10 and 31 have been amended such that the reference template is a waveform segment from a single ECG signal (claims 1 and 10) or heartbeat signal


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(claim 31). Mlynash requires multiple electrical heart signals to construct a template, as he explains:

In an exemplary embodiment, about a hundred cardiac cycles of sixty-two channel ECG data are acquired during sinus rhythm or atrial overdrive pacing for use as template signal. Typically, more than ten cycles are used, often more than fifty for the construction of the QRST template. Fewer cycles may be used if the spatial and temporal variations of the QRST complexes are relatively low. In general, at least two cardiac cycles of template signals can be used.

Mlynash, col. 9, lines 3-11. *See also* col. 2, lines 58-61 and claim 1. The reason that Mlynash uses multiple beats is to identify a “dominant QRS morphology ... from the pooled data” (Mlynash, col. 9, lines 46-61). The multiple beats are “adapted” and “filtered” to correct for differences in heart rate and voltage amplitude (Mlynash, col. 5, lines 5-27), respiratory baseline drift, high frequency artifacts, and line frequency interference (Mlynash, col. 9, lines 14-21). The present claims take the opposite approach to solving these problems of heart beat signal variation. Rather than acquire multiple signals, which are adapted to construct a template as in Mlynash, amended claims 1-3, 7-20, 26, 31-44 and 50-57 recite a single ECG signal template. The single ECG signal template is selected such that as “the cycle length and hemodynamic conditions of this beat are the closest to those of the ... beat that contains [the arrhythmia]” (specification, page 12, lines 15-21). The signals most likely to have the closest hemodynamic conditions to the signal to be studied are the signals immediately preceding or following the arrhythmia signal (specification, page 12, line 15 to page 13, line 9). Mlynash does not disclose or suggest a single signal template. In fact, Mlynash teaches the opposite, i.e., a multiple signal

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template that is “adapted” such as by resampling and modulating (Mlynash, col. 11, lines 43-45). Thus, amended claims 1, 10, 31, and the claims dependent thereon (i.e., claims 2, 3, 7-9, 11-20, 26, 32-44, 50, 54, and 56), are not anticipated by, or obvious over, Mlynash and this rejection should be withdrawn.

Claims 51-53 are directed to methods wherein a pace mapping catheter is maneuvered in the heart. Mlynash discloses “a non-invasive localization, characterization and classification apparatus and method for cardiac arrhythmias.” Mlynash, abstract, *see also, e.g.*, Mlynash, col. 3, lines 36-38; col. 4, lines 41-43; and col. 6, lines 55-58 (emphasis added). Thus, Mlynash discloses sensors *external* to the body (i.e., on the skin) (Mlynash, col. 7, lines 34-47). Because pace mapping in the heart is an invasive procedure involving sensors within the heart, Mlynash does not anticipate claims 51-53 and this rejection should be withdrawn. Neither does Mlynash suggest real-time comparisons of a template signal to a signal acquired from a pace-mapping catheter within the heart and, thus, Mlynash does not render obvious the subject matter of claims 51-53. For similar reasons, Mlynash does not anticipate or render obvious claims 55 and 57, which require an intracardiac lead. A lead within the heart is invasive and, therefore, claims 55 and 57 are not anticipated by Mlynash.

The Rejection Under 35 U.S.C. §103

Claims 1, 2, 7, 8 and 9 have been rejected under 35 U.S.C. §103 as obvious over Groenewegen, U.S. Patent No. 6,556,860 (“Groenewegen”).

This rejection is respectfully traversed. Groenewegen discloses a method for developing a database of body surface maps of flutter waves for the classification of atrial flutter. *See, e.g.*, Groenewegen, abstract. Groenewegen does not disclose or suggest a method for

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